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Guidance for the Reregistration of Pesticide Products Containing Chlorobenzilate as the Active Ingredient

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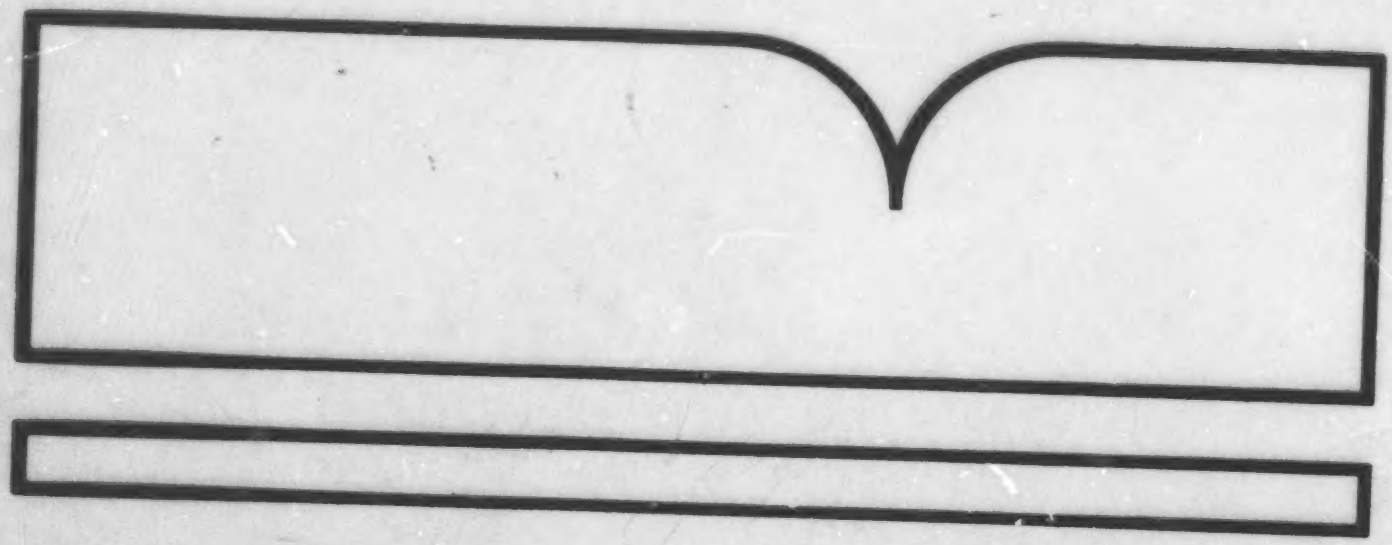

U.S. Department of Commerce
National Technical Information Service
NTIS

PB85-107605

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING CHLOROBENZILATE AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE AND TOXIC SUBSTANCES
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION

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This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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(See ANSI-Z39.18) See Instructions on Reverse OPTIONAL FORM 272 (4-77) (Formerly NTIS-35) Department of Commerce

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INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic

suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time-frames outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION

A. INTRODUCTION

This guidance document describes the Agency's regulatory position on registration of manufacturing use products (MPs) containing the miticide chlorobenzilate. The Agency's position is based on an evaluation of all registered uses and registered MP's with chlorobenzilate as the sole active ingredient. The document also considers known chemical and toxicological properties of this chemical as well as the established tolerances for residues in or on food and feed commodities. From these considerations the Agency sets forth the data and labeling requirements that must be met by registrants and applicants of chlorobenzilate products in order for the products to be reregistered or registered under this document. In order to be registrable under this document, technicals and manufacturing use products must list chlorobenzilate as the sole active ingredient. The tables accompanying this document list the data gaps which must be satisfied through submission of additional information. Future MPs that differ appreciably from those described in this document may require that amendments be made to this document to reflect the differences.

B. DESCRIPTION OF CHEMICAL AND USE PROFILE

Chlorobenzilate- $C_{16}H_{14}Cl_2O_3$; mol. wt. 325.20;
C.A.S. # 510-15-6, Shaughnessy # 028801.

Chlorobenzilate is the accepted common name for ethyl 4,4'-dichlorobenzilate. Trade names and other names include Acaraben™, Akar™, Folbex™, Geigy 338, Benzilan, Rospin and Kop-Mite.

Technical chlorobenzilate is a brownish viscous liquid. It has a boiling point of 141-142°C at 0.06mm Hg and a melting point of 35-37°C (pure material). At a temperature of 19.4°C, 86.9 grams of the technical material is soluble in 100 ml. of xylene. The material is virtually insoluble in water and infinitely miscible in benzene, acetone and other organic compounds. Under normal conditions, chlorobenzilate is stable at room temperature.

This miticide is produced in the United States by the Ciba-Geigy Corp. The chemical is also produced overseas by Nippon Kayaku Co., Japan and Makhteshim Beer-Sheva, Israel.

The federally registered formulated (end use) products containing chlorobenzilate are single active ingredient formulations. There are no mixtures with other active ingredients. Chlorobenzilate is commercially formulated as a four pound emulsifiable concentrate and the only registered use for the chemical is on citrus. This use is restricted to the states of Arizona, California, Florida and Texas. Foreign uses also include smokestrips for use in honey bee hives to control the bee-mite Acarapis woodi. In addition to the federal registrations, there remain three Florida intrastate products for use on citrus. There are no active Special Local Need registrations.

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on chlorobenzilate, the Agency has made the following determinations:

1. Neither this Agency nor the state of California has established a reentry interval for field workers entering treated fields. Considering acute toxicity alone, chlorobenzilate would not normally require a reentry interval. However, in keeping with established Agency policy for chemicals having an inadequate data base for evaluation of reentry exposure, and which have chronic toxic effects, a 24-hour reentry interval is now required. The registrant can either accept this interval or submit data to establish a different interval. This interval is conside ed provisional and the Agency reserves the right to revise this reentry interval and to impose additional label requirements after receipt and review of the data required in Table A and B of this Guidance Document.

2. Although the Agency is unable to complete a full tolerance reassessment because of certain residue chemistry and toxicology data gaps, the Agency concludes that no change in the present tolerance for citrus is warranted at this time. Additional residue data may necessitate a revision of this tolerance and the establishment of a food and/or feed additive tolerance(s).

3. Manufacturing-use products containing chlorobenzilate as a sole active ingredient may be registered for sale, distribution, reformulation, and use, under the terms and conditions set forth in this Guidance Document.

4. Registrants must provide or agree to develop additional data, as specified in the tables attached to this Guidance Document in order to maintain existing registrations or to obtain new registrations of substantially similar MPs.

5. On May 26, 1976, the EPA published in the Federal Register (41 FR 21517) a Notice of Rebuttable Presumption Against Registration and Continued Registration (RPAR) of pesticide products containing chlorobenzilate. The Agency concluded that the chemical induced oncogenic effects in experimental mammals. The Agency's position was not successfully rebutted.

Since chlorobenzilate has been determined to pose an oncogenic risk, this chemical "triggers" criteria for unreasonable adverse effects listed in Section 162.11 (a) of Title 40 of the U.S. Code of Federal Regulations. The Agency has concluded, via the RPAR process (Federal Register (44 FR 9548) February 13, 1979, " Notice of Intent to Cancel Registrations and Deny Applications for registration of all non-citrus chlorobenzilate uses," that by limiting the use to citrus, classifying chlorobenzilate products for restricted use, and by upgrading the protective clothing requirements, the exposure level and risks would be lowered to acceptable levels. The benefits were determined to exceed the risks and the chemical was allowed continued use under the terms set forth in our "Notice of Intent to Cancel or Deny" published in

1979. These RPAR findings have been confirmed in this review. However, other gaps in the data base preclude the completion of the Agency's total risk assessment for this pesticide chemical. Registrants had to comply with certain labeling changes and agree to develop and submit to this Agency the following residue and exposure studies:

Residue Chemistry and Exposure Studies

*a. Citrus Fractionation Study
*b. Feeding Citrus By-Products to Cattle Study (Ruminant Feeding Study)
**c. Residue Monitoring of Milk from Pulp Fed Cattle and Residue Monitoring of By-Products of Citrus Processing
d. Citrus Pickers Exposure Study
e. Aerial Applicator Exposure Study
***f. Ground Applicator Exposure Study

The Agency received little response from registrants concerning the filling of the above data gaps. Consequently, on July 22, 1982 this Agency mailed a 3(c)(2)(B) "Data Call in Notice" to all registrants requiring that certain "generic" and the above residue and exposure

* If residues concentrate in citrus pulp additional ruminant feeding studies may be required.

** This study has been eliminated since this information can be obtained in the Citrus Fractionation and Feeding Citrus By-Product to Cattle study as proposed in protocols submitted by Ciba-Geigy in February of 1980.

*** This study has been submitted by Florida Citrus Mutual and is no longer considered a data gap.

data be filled. As outlined in that document, time frames and schedules for the submission of these data were to be maintained and periodic reports were to be prepared and sent to the Agency. To date the need for one study has been eliminated, one study has been submitted, and protocols have been received and reviewed for two studies. All registrants of chlorobenzilate products remain bound by this document and the time frames for the completion of the data have been incorporated into Table A of this guidance document. These data are indicated by an asterisk in the footnotes of the tables.

6. The Agency has received a report indicating the presence of manufacturing impurities at relatively low levels in one technical chlorobenzilate product. The identified impurities include certain isomers and analogs of DDT. However, the analytical method used in this study was not provided and did not quantify the compounds identified. Since DDT and other related compounds are of substantial concern to the Agency, all registrants will be required to quantify their contaminants at the lowest level of detection using the best available technology.

D. REGULATORY RATIONALE

The Agency has determined that registration of chlorobenzilate should continue after considering the following:

1. Adequate studies are available to assess the acute oral and dermal toxicological effects of this chemical to humans.

2. Chlorobenzilate was found to be oncogenic. This finding was based mainly on an oncogenicity screening study reported by Kotin, Falk, Pallotta et al.(1969) and a study reported by Hazleton Laboratories (Horn, 1954). Additionally, a study by Hollingsworth, Woodard, and Woodard (1966) and an NCI report (Hazleton, 1978) were cited in the Agency's "Notice of Intent to Cancel."

Rebuttals to the oncogenicity "trigger" successfully eliminated the Horn (1954) and the Hollingsworth, Woodard and Woodard (1966) studies but not the Kotin, Falk and Pallatta et al. nor the NCI study. The Carcinogen Assessment Group (CAG) concluded that there was a small, but real, oncogenic risk to users. All uses of chlorobenzilate were cancelled except for citrus in an effort to reduce exposure. Labeling changes were required and the applicator protective clothing requirements were upgraded (see Section G) to further reduce this exposure.

The data show that the populations at risk with respect to chlorobenzilate use include pesticide applicators and citrus pickers. These populations are exposed to the chemical at the time of application and/or for a period of time following application. The Agency has selected restricted use classification and reentry intervals as a means of reducing exposure to these populations.

The key concept behind the restricted use classification is that certification can generally upgrade applicator skills and that with more skill and knowledge applicators are more likely to use pesticides carefully and efficiently. It would, therefore, be reasonable to conclude that a general upgrading of the skills of chlorobenzilate applicators would result in reduced exposure.

The data base for chlorobenzilate is inadequate for evaluation of reentry exposure to citrus pickers and other field workers. Therefore, establishment of a 24-hour reentry interval is in keeping with established Agency policy for chemicals having an inadequate data base for evaluating reentry exposure and which have chronic toxic effects.

3. A three generation rat reproduction study resulted in reduced testicular weights, however, the reproductive parameters were not affected at the dosage levels tested. The Agency in its RPAR conclusions required that registrants provide another multigeneration reproduction

study. This study has been received by the Agency and the results indicate that chlorobenzilate does not adversely affect reproductive performance nor produce "testicular atrophy" at dosage levels up to 100 mg/kg per day. This is no longer considered a data gap.

4. The current tolerance of 5 ppm on citrus is not adequately supported by residue data because the analytical procedure included an unacceptable extraction step. However, no adverse data have been submitted to the Agency suggesting that this tolerance level will not protect the public. Market basket surveys by the Food and Drug Administration show that residues in citrus have not exceeded the tolerance.

5. The most recent Pesticide Incident Monitoring Systems (PIMS) records available lists four pesticide incidents involving chlorobenzilate. However, none of these accidents could be wholly attributable to this chemical. No pesticide fatalities were involved and only two persons required medical attention.

6. The available data base is insufficient to fully assess the environmental fate of chlorobenzilate. However, since the data suggest that chlorobenzilate degrades fairly rapidly and both it and its degradates have low mobility, groundwater contamination is considered unlikely. Data on the octanol/water partition coefficient, volatility, leaching and reentry are required. Once the data gaps are filled, additional data may be required.

7. There are insufficient ecological effects data to complete a hazard assessment of the use of chlorobenzilate on citrus. When the Agency receives data from the required studies in this Guidance Document, a hazard assessment will be completed. Also, our analysis of these requested data may necessitate additional studies such as acute toxicity testing to estuarine and marine organisms. The amount of DDT and related compounds contaminating chlorobenzilate products is of special ecological concern and will mandate further investigation.

8. Under FIFRA, the Agency cannot cancel or withold registration simply because data are unavailable or inadequate (see Section 3(c) (2)(B) and 3(c)(7) of FIFRA). This Guidance Document provides a mechanism for identifying data needs and calling in these data. The data will then be evaluated and a determination will be made as to the continued registrability of this chemical.

E. Criteria for Products Subject to the Guidance Document

This Guidance Document covers pesticide products that contain chlorobenzilate as a sole active ingredient; the chart on page three describes the extent to which such products are subject to this Document. Applicants for registration or reregistration of such products must comply with all terms and conditions described herein. This includes making a commitment to fill data gaps on a schedule specified by the Agency. Also, applicants for reregistration must follow the instructions contained in this Guidance Document and complete and submit the appropriate forms within the specified times. End-use products must be in compliance with the label changes specified in this Document.

F. Acceptable Ranges and Limits

1. Product Composition Standards

To be fully covered under this Guidance Document, manufacturing use products (MP's) must contain chlorobenzilate as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits. However, because the Agency is concerned about possible DDT and related compounds as impurities in the technical material, quantification of these impurities must be at a level of detection below 0.1% of the technical using the best suitable validated analytical methods (preferably gas liquid chromatography or high performance liquid chromotography).

2. Acute Toxicity Limits

The Agency will consider for registration any MP whose acute toxicity category (I, II, III or IV) is supported by adequate acute toxicity data and labeling, including appropriate precautionary statements. The Agency has determined that the appropriate signal word for chlorobenzilate products is "CAUTION".

3. Use Patterns

To be registered under this Guidance Document, MP's may be labeled for formulation only into end-use products for citrus crops under the terrestrial nondomestic food crop uses (ground and aerial applications) grouping.

G. Required Labeling

All manufacturing-use products and end-use products containing chlorobenzilate must bear appropriate labeling as specified in 40 CFR 162.10. Additionally, these products must also comply with the labeling requirements outlined in the Agency's Notice of Intent to Cancel Registrations and Deny Applications for Registrations of Pesticide Products Containing Chlorobenzilate published in the Federal Register (44 FR 9548) February 13, 1979. Those requirements, as well as labeling requirements identified in the development of this document are set forth below.

When the data to be submitted under this Guidance Document have been reviewed, the Agency may impose additional labeling requirements.

1. Label Requirements for All Chlorobenzilate Products

"General Precautions"

"Take special care to avoid getting chlorobenzilate in eyes, on skin or on clothing. Avoid breathing vapors or spray mist If chlorobenzilate gets on clothing, remove contaminated clothing and wash affected parts of body with soap and water. If extent of contamination is unknown, bathe entire body thoroughly. Change to clean clothing. Wash hands with soap and water each time before eating, drinking or smoking. At the end of each work day, bathe entire body with soap and plenty of water. Wear clean clothes each day and launder before reusing."

"Handling Precautions"

"Heavy-duty rubber or neoprene gloves and apron must be worn during loading, unloading, and equipment clean-up."

2. Label Requirements for Manufacturing-Use Products

Statement of Environmental Hazards

"ENVIRONMENTAL HAZARDS"

"This pesticide is toxic to wildlife. Do not discharge into lakes, streams, ponds or public water except in accordance with a NPDES permit. For further guidance, contact the nearest EPA Regional Office."

3. Label Requirements for End-Use Products

a. The following "Restricted Use Statement" must be added to the label.

RESTRICTED USE PESTICIDE
For retail sale to and use only by certified applicator or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

b. The labeling must state, "This product is restricted to the states of Arizona, California, Florida and Texas."

c. "Required Clothing and Equipment for Application"

"One-piece overalls which have long sleeves and long pants constructed of finely-woven fabric as specified in the USDA/EPA Guide for Commercial Applicators. Wide brimmed hat. Heavy duty fabric work gloves. Any article which has been worn while applying chlorobenzilate must be cleaned before reusing. Clothing which has been drenched or has otherwise absorbed concentrated pesticide must be buried or burned"

"Facepiece respirator of the type approved for pesticide spray applications by the National Institute for Occupational Safety and Health. Instead of clothing and equipment specified above, the applicator can use an enclosed tractor cab which provides a filtered air supply (as described by Taschenberg and Bourke, 1975), and which allows no more than 0.41 mg/day total exposure to chlorobenzilate. For aerial applicators: Aerial application may be conducted without the specified clothing and equipment."

d. Statement of Environmental Hazards

"ENVIRONMENTAL HAZARDS"

This product is toxic to wildlife. Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes.

e. Reentry Statement

"Do not enter treated citrus groves within 24 hours."

H. Tolerance Reassessment

Based on the established tolerances published in 40 CFR 180.109, the theoretical maximum residue contribution (TMRC) from chlorobenzilate residues to the human diet is calculated to be 0.7017 mg/day from a 1.5 kg food diet for a 60 kg person. Because all uses of chlorobenzilate except citrus have been cancelled, the Agency has recalculated the TMRC, Acceptable Daily Intake (ADI) and Maximum Permissible Intake (MPI). These values are 0.2859 mg/day/1.5 kg (3.81% of the ADI), 0.125 mg/ kg/day and 7.50 mg/day/60 kg, respectively. These ADI and MPI values are all considered provisional since a data gap exists for a chronic feeding study in a second species. Another reassessment and recalculation of the ADI and MPI will be done when studies required to fill the toxicology data gaps have been submitted and validated. If different values are obtained then the ratio between the MPI and TMRC will be reviewed. It is possible, at that time, that the established tolerances may be affected.

According to 40 CFR 180.109, tolerances are established on residues of chlorobenzilate in or on raw agricultural commodities as follows:

15 ppm in or on almond hulls,
5 ppm in or on apples, citrus fruits, melons and pears,
0.5 ppm in or on cottonseed,
0.5 ppm in or on meat, fat, and meat byproducts of cattle and sheep,
0.2 ppm in or on almonds and walnuts.

The tolerances for apples, melons, pears, cottonseed, almond hulls, almonds and walnuts were established for residues resulting from uses on these commodities. These uses were cancelled and the tolerances are scheduled to be revoked in fiscal year 1984. The tolerance for meat, fat, and meat byproducts of cattle and sheep will be retained to cover residues resulting from citrus use.

Residue data on citrus processed commodities (molasses, pulp, and oil) will be required showing the amount of residues present. If the residues are found to concentrate in processed commodities, a petition for a food additive tolerance(s) will have to be submitted or this use must deleted from the label. This requirement was not in place when the original tolerance for citrus was approved. Also, additional ruminant feeding studies may be required.

International Tolerances

The following tolerances for residues of chlorobenzilate have been established in:

Canada:	5 ppm apples, cantaloupes, citrus fruits, pears
Mexico:	5 ppm citrus fruits, apples, melons, pears
	0.5 ppm cotton(seed)
	0.2 ppm nuts

The latest Codex Alimentarius entry and tolerances for chlorobenzilate are:

Crop	Maximum Residue limit (Mg/Kg)	
Almonds	0.2	shell-free basis
Apples	5.0	
Cantaloupe	1.0	
Citrus fruit	1.0	
Grapes	2.0	
Melons	1.0	
Milk	0.05	
Pears	2.0	
Tomato	0.2	
Walnuts	0.2	shell-free basis

The Maximum Residue Limit for citrus is not currently in harmony with the established tolerances for citrus fruit in the U.S.A., Mexico and Canada. Until the residue data requested for citrus use is submitted and reviewed to determine the appropriate tolerance level, the lowering of the current 5 ppm tolerance level is not warranted.

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)
to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition[1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry				
Product Identity:				
61-1 - Identity of Ingredients	TGAI	Partially	00077423, 00077438[a], GS0075080[b]	Yes[3,4]
61-2 - Statement of Composition	TGAI	Partially	00077438[a], GS0075080[b]	Yes[3,4]
61-3 - Discussion of Formation of Ingredients	TGAI	Partially	00077443[a], 0007740[5] 00077411, GS0075080[b]	Yes[3,4]
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis	TGAI	Partially	GS0075080[b]	Yes[5,6]
62-2 - Certification of Limits	TGAI	Partially	GS0075080[b]	Yes[6]
62-3 - Analytical Methods for Enforcement of Limits	TGAI	Partially	00077435, 00077442[a] GS0075079[b], GS0075080[b]	Yes[10]
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00077423, 00077411	Yes[6]
63-3 - Physical State	TGAI	Yes	00077423, 00077411	Yes[6]
63-4 - Odor	TGAI	No	-	Yes
63-5 - Melting Point	TGAI	N/A	-	No[7]
63-6 - Boiling Point	TGAI	Yes	00077423, 00077411	Yes[6]
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	Yes	00077423, 00077411	Yes[6]

a. Data submitted by Makhteshim Beer-Sheva Chem. Works, Ltd. These data may be compensable.
b. Data submitted by Ciba-Geigy. These data may be compensable.

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
63- 8 - Solubility	TGAI OR PAI	Yes	00077423, 00077411 GS0075080[b]	Yes[6]
63- 9 - Vapor Pressure	PAI	Yes	00077423, 00077411	Yes[6]
63-10 - Dissociation constant	PAI	No	-	Yes
63-11 - Octanol/water partition coefficient	PAI	No	-	Yes
63-12 - pH	TGAI	N/A	-	No[8]
63-13 - Stability	TGAI	Partially	00077423, 00077411	Yes[6]
Other Requirements:				
64- 1 - Submittal of samples	TGAI	No	-	No[9]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2]
§158.120 Product Chemistry (continued)				

1. Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; Choice = Choice of several test substances determined on a case-by-case basis.
2. Data must be submitted no later than three months.
3. Updated information must be supplied on identity and quantity of impurities and inerts. A comparison of the confidential statements of ingredients show that there is a good possibility for the presence of DDT and/or related compounds (DDE) as impurities in the technical material. Quantification must be made with a sensitivity below 0.1% of the technical material.
4. Data submitted by Ciba-Geigy and Makhteshim. All others must submit these data.
5. Analysis of at least five production batches is required.
6. Data submitted by Ciba-Geigy. All others must submit these data.
7. Since the material is liquid, no data are required.
8. Since chlorobenzilate is insoluable in water, no pH data are required.
9. The Agency will request samples when the need arises.
10. No validation data for any of the methods were submitted. These data are required. If the DDT-like impurities were detected by T.L.C., a description of the method should be submitted as well as adequate validation data. (Preferrably we require data by HPLC or Mass Spec.)

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirements	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	00077457	Yes[3]
- Livestock	PAIRA and plant metabolites	Partially	00077400	Yes[4]
171-4 - Residue Analytical Method				
- Plant residues	TGAI and metabolites	Yes	00078289, 00077407	No[5]
- Animal residues	TGAI and metabolites	Yes	GS0075035, 00077402	No[5]
171-4 - Storage Stability Data	PAI	Yes	00077423, 00077411	No
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use				
Citrus Fruits	TEP	Partially	00077457, 00077448 00077416, 00077470 00077445	Yes[6,9]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.125 Residue Chemistry				
171-4 - Magnitude of the Residues- Residues Studies for Each Food Use (con't)				
Meat/milk/poultry/eggs	TGAI or plant metabolites	Partially	00078288, 00077434 00077384	No[7]
Processed Commodities				
Citrus Molasses	TGAI	No	-	Yes[8]
Citrus pulp, dried	TGAI	No	-	Yes[8]
Citrus oil	TGAI	No	-	Yes[8]

1. Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product; EP = End-use product.
2. Data must be submitted no later than 36 months
3. Metabolism data are required which determine the extent of metabolism, degradation and/or breakdown of chlorobenzilate in citrus.
4. A ^{14}C radioactive metabolism study in a large ruminant is required.
5. If additional metabolism data show concern for the presence of possible metabolites, then alternate methodology may be required.
6. Data should be submitted which reflects resulting residue levels in or on the whole fruit (oranges, lemons, grapefruit) from the maximum recommended label rates including aerial applications and repeat (3 or more) applications.
7. Large animal and poultry radiolabelled metabolism studies are needed. Depending on the results of these studies and the results of the processing study, additional feeding studies and/or a tolerance for meat, milk, poultry and and eggs may be required.
8. If residues are found to concentrate in processed commodities, a food and/or feed additive tolerance will be required and additional ruminant feeding studies may be required.
*9. A citrus fractionation study is needed. This study must be submitted by February of 1984.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB:					
161-1 - Hydrolysis	TGAI or PAIRA	A	No	-	Yes
Photodegradation					
161-2 - In water	TGAI or PAIRA	A	No	-	Yes
161-3 - On soil	TGAI or PAIRA	A	No	-	Yes
161-4 - In Air	TGAI or PAIRA	A	No	-	Yes
METABOLISM STUDIES-LAB:					
162-1 - Aerobic Soil	TGAI or PAIRA	A	Partially	00049143[b], GS0075041	Yes[4]
162-2 - Anaerobic Soil	TGAI or PAIRA	A	N/A	-	No[5]
162-3 - Anaerobic Aquatic	TGAI or PAIRA	A	N/A	-	No[6]
162-4 - Aerobic Aquatic	TGAI or PAIRA	A	N/A	-	No[6]
MOBILITY STUDIES:					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A	No	-	Yes
163-2 - Volatility (Lab)	TEP	A	No	-	Yes
163-3 - Volatility (Field)	TEP	A	No	-	Yes

b. Data submitted by Ciba-Geigy. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A	Partially	00077368[b]	Yes[7]
164-2 - Aquatic (Sediment)	TEP	-	N/A	-	No[8]
164-3 - Forestry	TEP	-	N/A	-	No[9]
164-4 - Combination and Tank Mixes	-	-	N/A	-	No[10]
164-5 - Soil, Long-term	TEP	A	No	-	Yes
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	N/A	-	No[11]
165-2 - Rotational Crops (Field)	TEP	A	N/A	-	No[11]
165-3 - Irrigated Crops	TEP	A	N/A	-	No[12]
165-4 - In Fish	TGAI or PAIRA	A	No	-	Yes[13]
165-5 - In Aquatic Non-Target Organisms	TEP	A	No	-	Reserved[14]

b. Data submitted by Ciba-Geigy. These data may be compensable.

GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.130 Environmental Fate (Continued)					

1. Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
2. The use pattern is coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoors; I= Indoor.
3. Data must be submitted no later than 36 months.
4. Data are required identifying the degradation products and their rates of degradation.
5. This study is not required for this use pattern in the guidelines.
6. Data required only for aquatic uses.
7. Data are required on one, preferably two domestic soils where the pesticide is to be used.
8. There are no registered aquatic impact uses.
9. There are no registered forestry uses.
10. This guidance document deals only with single active ingredients.
11. Citrus is not considered a rotational crop.
12. Not required if citrus is treated conventionally with the pesticide. This study is required if the pesticide is intentionally added to the irrigation water.
13. Fish accumulation studies are not required if the registrant can show that the active ingredient or its principal degradation product(s) will not reach water, persist in water or accumulate in tissues of animals.
14. These data are required only if data from §165-4 shows potential for residues of chlorobenzilate to accumulate.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Use Patterns [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral LD_{50} - Rat	TGAI	A	Yes	00080422A	No
81-2 - Dermal LD_{50}	TGAI	A	Yes	00080422A	No
81-3 - Inhalation LC_{50} - Rat	TGAI	A	No	-	Yes
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	A	No	-	No[4]
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A	Yes	00077463	No
82-2 - 21-Day Dermal	TGAI	A	No	-	No[5]
82-3 - 90-Day Dermal	TGAI	A	No	-	No[5]
82-4 - 90-Day Inhalation - Rat	TGAI	A	No	-	No[6]
82-5 - 90-Day Neurotoxicity-Hen/Mammal	TGAI	A	No	-	No[4]

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)[3]
§158.135 Toxicology (continued)					
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A	Partially	00077463	Yes[7]
83-2 - Oncogenicity Study - 2 species: Rat and Mouse preferred	TGAI	A	Yes	GS0075001	No
83-3 - Teratogenicity - 2 species	TGAI	A	No	-	Yes[8]
83-4 - Reproduction, 2-generation	TGAI	A	Yes	GS0075081[b]	No
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A	No	-	Yes
84-2 - Chromosomal Aberration	TGAI	A	No	-	Yes
84-2 - Other Mechanisms of Mutagenicity	TGAI	A	No	-	Yes

b. Data submitted by Ciba-Geigy. These data may be compensable.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisty This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.135 Toxicology (continued)					
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A	Yes	00075003	No
85-2 - Domestic Animal Safety	Choice	A	N/A	-	No[9]

1. Composition: TGAI= Technical grade of the active ingredient.
2. The use pattern is coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food Crop; C= Aquatic, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic, Outdoor; I= Indoor.
3. Data must be submitted no later than 36 months.
4. This study is not required because the chemical is not an organophosphate and is is not structurally related to a substance that causes delayed neurotoxicity.
5. Not required because the acute dermal toxicity is Category III.
6. Not required. This use does not result in repeated inhalation exposure.
7. Testing requires a rodent and a non-rodent species. A rodent study is still needed.
*8. These data are required to be submitted by October of 1984.
9. Not required because there are no domestic animal uses.

GENERIC DATA REQUIREMENTS FOR CHLORBENZILATE

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral LD_{50}	TGAI	A	No	-	Yes
71-2 - Avian Dietary LC_{50}	TGAI	A	No	-	Yes
71-3 - Wild Mammal Toxicity	TGAI	A	No	-	Reserved[4]
71-4 - Avian Reproduction	TGAI	A	No	-	Yes
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A	No	-	Reserved[4]
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish LC_{50}	TGAI	A	No	-	Yes
72-2 - Acute LC_{50} Freshwater Invertebrates	TGAI	A	No	-	Yes
72-3 - Acute LC_{50} Estuarine and Marine Organisms	TGAI	A	No	-	Yes
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A	No	-	Yes
70-1(d) Reptile and Amphibian LC_{50}	TGAI	A	No	-	Reserved[4]

TABLE II

GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.145 Wildlife and Aquatic Organisms (continued)					
72-5 - Fish - Life-Cycle	TGAI	A	No	-	Yes
72-6 - Aquatic Organism Accumulation	TGAI, PAI OR Degradation Product	A	No	-	Reserved[4]
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A	No	-	Reserved[4]

1. Composition: TGAI = Technical grade of the active ingredient; PAI = pure active ingredient; TEP = Typical end-use product;
2. The use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial Non-Food Crop; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; H= Domestic Outdoor; I= Indoor.
3. Data must be submitted no later than 36 months.
4. Reserved pending the outcome of the five basic studies (ecological effects), environmental fate data, toxicology data and residue chemistry data. When these respective studies have been evaluated then a determination will be made as to whether or not additional studies are required in order to complete a hazard assessment of the citrus use pattern.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honey bee acute contact LD_{50}	TGAI	A	Yes	00036935	No
141-2 - Honey bee - toxicity of residues on foliage	TEP	A	No	-	No[4]
141-3 - Wild bees important in alfalfa pollination - toxicity of residues on foliage	TEP	A	N/A	-	No[5]
141-4 - Honey bee subacute feeding study		A	N/A	-	Reserved[6]
141-5 - Field testing for pollinators	TEP	A	No	-	No[4]

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition[1]	Use 2 Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.155 Nontarget Insect (continued)					
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects		A			Reserved[7]
142-2 - Aquatic insect life-cycle study		A			Reserved[7]
142-3 - Simulated or actual field testing for aquatic insects		A			Reserved[7]
143-1 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES thru 143-3		A			Reserved[7]

1. Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2. The use pattern is coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I= Indoor.
3. Data must be submitted no later than 36 months.
4. An acute contact LD_{50} test shows chlorobenzilate is non-toxic to honey bees, no further testing is required.
5. Required only if pesticide is intended for foliar application to seed alfalfa.
6. Reserved pending development of test methodology.
7. Reserved pending Agency decision as to whether the data requirement should be established.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirement	Composition [1]	Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A	Partially	GS0075082	Yes[5,6]
132-1 - Soil Dissipation	TEP	A	No	-	No[4]
133-3 - Dermal Exposure	TEP	A	Partially	GS0075002, GS0075082	Yes[5,6]
133-4 - Inhalation Exposure	TEP	A	No	GS0075082	Yes[5,6]

1. Composition: TEP= Typical end use product.
2. The use pattern is as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic, Outdoor; I= Indoor.
3. Data must be submitted no later than 36 months.
4. A field dissipation study is required. Those results should satisfy this requirement.
*5. Citrus picker, and aerial applicator exposure data are required. These data may suffice for this requirement. These data must be submitted by February of 1984.
6. An interim 24 hour reentry interval is required pending the submission and evaluation of reentry data.

TABLE A
GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirements	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.150 Plant Protection					
121-1 - TARGET AREA PHYTOTOXICITY	EP	A	No	-	No[3]
NONTARGET AREA PHYTOTOXICITY					
TIER I					
122-1 - Seed Germination/ Seedling Emergence	TGAI	A	No	-	No[3]
122-1 - Vegetative Vigor	TGAI	A	No	-	No[3]
122-2 - Aquatic Plant Growth	TGAI	A	No	-	No[3]
TIER II					
123-1 - Seed Germination/ Seedling Emergence	TGAI	A	No	-	No[3]
123-1 - Vegetative Vigor	TGAI	A	No	-	No[3]
123-2 - Aquatic Plant Growth	TGAI	A	No	-	No[3]
TIER III					
124-1 - Terrestrial Field	TEP	A	No	-	No[3]
124-2 - Aquatic Field	TEP	A	No	-	No[3]

GENERIC DATA REQUIREMENTS FOR CHLOROBENZILATE

Data Requirements	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.150 Plant Protection (Continued)					

1. Composition: TGAI= Technical grade of the active ingredient; TEP= Typical end-use product. EP= End-use product.
2. The use pattern is coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I= Indoor.
3. These requirements are generally waived unless it is believed there is a phytotoxicity problem.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE ...

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry				
Product Identity				
61-1 - Identity of Ingredients	MP	Partially	00077423, 00077438[a] GS0075080[b]	Yes[3,4]
61-2 - Statement of Composition	MP	Partially	00077438[a], GS0075080[b]	Yes[3,4]
61-3 - Discussion of Formation of Ingredients	MP	Partially	00077443[a], 00077405 00077411, GS0075080[b]	Yes[3,4]
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis	MP	Partially	GS0075080[b]	Yes[5,6]
62-2 - Certification of Limits	MP	Partially	GS0075080[b]	Yes[6]
62-3 - Analytical Methods for Enforcement of Limits	MP	Partially	00077435, 00077442[a] GS0075079[b], GS0075080[b]	Yes[9]
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	00077423, 00077411	Yes[6]
63-3 - Physical State	MP	Yes	00077423, 00077411	Yes[6]
63-4 - Odor	MP	No	-	Yes
63-7 - Density, bulk density, or specific gravity	MP	Yes	00077423, 00077411	Yes[6]

a. Data submitted by Makhtishem Beer-Sheva Chem. Works, Ltd. These data may be compensable.
b. Data submitted by Ciba-Geigy. These data may be compensable.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLOROBENZILATE

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]
§158.120 Product Chemistry (continued)				
63-12 - pH	MP	N/A	-	No[7]
63-14 - Oxidizing or reducing action	MP	No	-	Yes
63-15 - Flammability	MP	No	-	Yes
63-16 - Explodability	MP	No	-	Yes
63-17 - Storage Stability	MP	No	-	Yes
63-18 - Viscosity	MP	No	-	Yes
63-19 - Miscibility	MP	No	-	Yes
Other Requirements				
64- 1 - Submittal of Samples	MP	No	-	No[8]

1. Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.
2. Data must be submitted no later than three months.
3. Updated information must be supplied on identity and quantity of impurities and inerts. A comparison of the confidential statements of ingredients show that there is a good possibility for the presence of DDT and/or related compounds (DDE) as impurities in the technical material. Quantification must be made with a sensitivity below 0.1% of the technical material.
4. Data submitted by Ciba-Geigy and Makhteshim. All others must submit these data
5. Analysis of at least five production batches is required
6. Data submitted by Ciba-Geigy. All others must submit these data.
7. Since chlorobenzilate is insoluable in water, no pH data are required.
8. The Agency will request samples when the need arises.
9. No validation data for any of the methods were submitted. These data are required. If the DDT-like impurities were detected by T.L.C., a description of the method should be submitted as well as adequate validation data. (Preferrably we require data by HPLC or Mass Spec.)

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLOROBENZILATE

Data Requirement	Composition [1]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? [2]
§158.135 Toxicology				
ACUTE TESTING				
81-1 - Oral LD_{50} - Rat	MP	Yes	00080422A	No
81-2 - Dermal LD_{50}	MP	Yes	00080422A	No
81-3 - Inhalation LC_{50} - Rat	MP	No	-	Yes
81-4 - Primary Eye Irritation - Rabbit	MP	No	-	Yes
81-5 - Primary Dermal Irritation	MP	No	-	Yes
81-6 - Dermal Sensitization	MP	No	-	Yes

1. Composition: MP = Manufacturing-use product.
2. Data must be submitted no later than 36 months.

IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This chapter applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10], as indicated by the following paragraphs of this chapter of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

A. Label Contents

40 CFR §162.10 requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. [40 CFR §162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Mr. Robert J. Taylor, Product Manager
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-1800

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author.

When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library," followed by an alphabetic suffix which

shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION GUIDANCE DOCUMENT BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registration Under this Guidance Document

00017801 Kotin, P.; Falk, H.; Pallotta, A.J.; et al. (1968) Evaluation of Carcinogenic, Teratogenic, & Mutagenic Activities of Selected Pesticides and Industrial Chemicals: Vol. 1. Bethesda, Md.: Bionetics Research Laboratories. (Report No. NCI-DCCP-CG-1973-1-1; incomplete study; also In unpublished submission received Mar 17, 1976 under 38329-2; submitted by Consolidated Chemical, Co., Denver, Colo.; CDL:225259-N)

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00075003 R. Schattner Company (1966) Tests with Ristex to Control Various Organisms. (Compilation; unpublished study received May 28, 1964?; Jun 9, 1966 under 8383-1; CDL:050703-B)

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00077368 Guth, J.A.; Senn, U.; Imhof, R. (1975) Chlorobenzilate (G-23992): Dissipation of Residues of Chlorobenzilate and Two of Its Metabolites in a Silty Loam Soil after Application of AKAR 50 EC: No. RVA 323/75. (Unpublished study received Oct 28, 1976 under 100-458; prepared by Ciba-Geigy, Ltd., Switzerland, submitted by Ciba-Geigy Corp., Greensboro, N.C.; CDL:226572-C)

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00077402 Harris, H.J. (1955) Colorimetric determination of ethyl 4,4'-dichlorobenzilate (chlorobenzilate) as a spray residue. Journal of Agricultural and Food Chemistry 3(11):939-941. (Also In unpublished submission received Dec 27, 1967 under 8F0685; CDL: 092990-D)

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00077407 Geigy Chemical Corporation (19??) The Determination of Chlorobenzilate and Chloropropylate in Plant Materials. Ardsley, N.Y.: Geigy. (Analytical bulletin no. 9; also In unpublished submission received Feb 4, 1966 under 9H0007; CDL:221563-C)

00077411 Geigy Chemical Corporation (19??) Chlorobenzilate--Chloropropylate Petition: Section A: Name, Chemical Identity and Composition of Chlorobenzilate and Chloropropylate. (Unpublished study received Sep 30, 1966 under 6F0463; CDL:092752-B)

00077413 Hollingsworth, R.L.; Woodard, M.W.; Woodard, G. (1966) Chlorobenzilate Safety Evaluation by Dietary Feeding to Rats for 104 Weeks. Final rept. (unpublished study received Sep 30, 1966 under 6F0463; prepared by Woodard Research Corp., submitted by Geigy Chemical Corp., New York, N.Y.; CDL:090513-A)

00077416 Wolfenbarger, D.O. (1962) Chlorobenzilate Residues--Limes: AG-A 324. (Unpublished study received Sep 30, 1966 under 6F0463; prepared in cooperation with Univ. of Florida, Subtropical Experiment Station, submitted by Geigy Chemical Corp., New York, N.Y.; CDL:090513-D)

00077423 Geigy Chemical Corporation (19??) Chlorobenzilate Formulations. Ardsley, N.Y.: Geigy. (Chlorobenzilate technical bulletin no. 61-1; also In unpublished submission received Jun 16, 1963 under PP0379; CDL:092665-C)

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00077470 Geigy Chemical Corporation (1957) Chlorobenzilate Residues from Grapefruit, Tangerines and Oranges. (Compilation; unpublished study received on unknown date under PP0182; CDL:090210-B)

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00078289 Blinn, R.C.; Gunther, F.A.; Kolbezen, M.J. (1954) Microdetermination of the acaricide ethyl p , p -dicholorobenzilate (chlorobenzilate). Journal of Agricultural and Food Chemistry 2(21): 1080-1083. (Also In unpublished submission received Feb 5, 1955 under PP0013; submitted by Geigy Chemical Corp., New York, N.Y.; CDL:092297-D)

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GS0075080 Ciba-Geigy (1983) Additional Information of DDT-like Impurities Found in Chlorobenzilate Technical and Supporting Methodology (unpublished).

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APPENDIX II-2

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

APPENDIX II-3

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				

63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D U.S.	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	.6 point
Above 10 to 15	.8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
(kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing Chlorobenzilate as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the steps you must take to maintain registration for your product(s).

Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.

2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.

3. Sets out time-frames for submission of required data.

4. Explains how to revise labeling for maufacturing use products. (As the Guidance Document explains, labeling is not required at this time.)

5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that <u>if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended</u>.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Robert J. Taylor, Product Manager 25
Environmental Protection Agency
Registration Division (TS-767)
Office of Pesticide Programs
Washington, D.C. 20460
Telephone 703/557-1800

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure

ATTACHMENT A

PRODUCTS AFFECTED BY THIS REREGISTRATION PROCESS

Following is a list of your products affected by this reregistration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

EPA Reg. No.	Product Name

ATTACHMENT B

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING THE ACTIVE INGREDIENT

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company address, active ingredient, percentage of active ingredient and type of formulation, such as Manufactucturing-Use Product (MP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).